REMARKS

Attention is respectfully drawn to co-pending application serial number 10/942,230, and the written remarks submitted in that case on August 15, 2006. It is respectfully noted that the art cited in the outstanding office action in this application was also discussed during the interview of August 15, 2006 regarding related cases 10/942,230 and 10/390,070. The Examiner's efforts to handle these cases and serial number 11/056,665 concurrently and to expedite prosecution of all four cases are greatly appreciated. The Examiner is also thanked for his kind offer to take note of the art submitted via information disclosure statements and/or made of record in serial numbers 10/942,230, 10/390,070 and 11/056,665, rather than require applicants to submit the same information in all of the cases. Should the Examiner require additional copies of any documents, the undersigned would be pleased to immediately provide same via whatever mode is requested by the Examiner, whether it be facsimile, email, post and/or courier.

ELECTION / RESTRICTION

Applicant respectfully affirms the election made during the 26 September 2006 telephone conference with the Examiner. New dependent claims 31 and 32 depend from elected claims 21 and 22 and are submitted in place of canceled claims.

REJECTIONS UNDER 35 USC §112

Claims 11, 12 and 15 have been amended to address the problems noted in the Office Action, while claims 13 and 14 have been deleted.

REJECTIONS UNDER 35 USC §102

Withdrawal of the rejection of claims 1-3, 15, 17 and 26-28 under 35 USC §102 based on anticipation by US Patent 4,463,755 to Suzuki ("Suzuki") is respectfully requested as Suzuki does not teach pleated tubing as recited in the pending claims (pleated tubing is also referred to as accordion-like tubing; the pleats permit a tube to be axially extended or compressed to a new length and to maintain the new length when the tension or compression force is removed). Although page 4, section 10, of the

Office Action states that Suzuki teaches "pleated or corrugated tubing (col. 5, lines 26-39)," pleated tubing is not taught or suggested by Suzuki. The Office Action confirms this on page 5, section 13:

> Suzuki teaches the first and second conduits formed from corrugated tubing (col. 5, lines 26-39) but is silent with regards to conduits being able to retain its shape after axial expansion or contraction.

Suzuki's corrugated tubing cannot retain its expanded or contracted length and/or shape after axial expansion and contraction, and Suzuki does not teach or suggest the use of pleated tubing.

REJECTIONS UNDER 35 USC §103

Claims 4-14, 16, 18-25, and 29 were rejected as obvious over Suzuki, issued August 7, 1984, in view of WO 85/05277 to Clawson et al., published December 5, 1985 ("Clawson") and/or US Patent 5,778,872 to Fukunaga et al., issued July 14, 1998 ("Fukunaga"). The last patent cited is to Dr. Atsuo Fukunaga, the principal inventor of this application. Claims 6-7, 10, 13-14, 19 and 23-24 have been canceled. Withdrawal of this rejection with respect to claims 4, 5, 8, 9, 11, 12, 18, 20-22, 25, and 29, and allowance of all of the pending claims, is respectfully requested for reasons set forth below.

Claim 1 is the only independent claim elected for examination. While the rejection under *35 USC §103* as stated in the Office Action would not apply to claim 1 provided the rejection under *35 USC §102* is overcome, the patentable features of all of the pending claims are addressed to expedite allowance. The combination of the following limitations in claim 1 are missing from the cited art, and it is respectfully submitted that it is not obvious to one of ordinary skill in the art to combine the teachings of the cited art to achieve the present invention: (1) a *unilimb* breathing circuit having first and second pleated tubes that carry inspiratory and expiratory gases, (2) the first and second pleated tubes being connected at their distal ends to a common distal fitting (i.e., they are proximal of the distal fitting), (3) the distal fitting being capable of detachable connection *directly* to a patient airway device selected from a mask, an endotracheal tube, a laryngeal mask, a laryngeal tube, and a nasal tube, and (4) the

breathing circuit meets the flow and compliance requirements for spontaneous and assisted ventilation. Additional limitations in the dependent claims further distinguish over the prior art. For example, Claims 2 and 5 are further limited by a common proximal fitting or terminal connected to the proximal ends of the expiratory and inspiratory gas conduits, while claims 11 and 12 recite one conduit being longer that the other, and claims 21, 22 and 25 recite filtration elements.

It is respectfully submitted that, even if the prior art could be combined as suggested in the Office Action (a combination for which there is no teaching, suggestion or motivation found in the cited art), such a combination would not lead to the claimed invention, unless hindsight and the teachings of the applicant's patent disclosure are used to further modify the combined teachings.

While breathing circuits appear to be simple constructs of tubing and fittings, the science underlying their development, use and improvements is complicated; inadequate function, improper design or construction, and/or damage to breathing circuits can lead to death or serious injury. Since breathing circuits supply both breathing air crucial to life as well as inhaled medications such as anesthetics, one of skill in the art is required to study complex biological systems, the physics of fluid and gas flow in the systems, and the chemistry of the system components and reactants. Thus, attempted improvements to breathing systems share the unpredictability of pharmaceutical research. Even small changes to prior art breathing circuits can lead to significant unexpected detrimental or beneficial effects, and significant research efforts, failures and expense are associated with making successful improvements to breathing circuits. While an improved breathing circuit may have only minor changes in tubing and fitting dimensions and configurations over the closest prior art, the large number of patents for breathing circuits and their components reflects the inventive and patentable merit often associated with what appear to be small breathing circuit modifications. Further, the prior art often goes in opposite directions. For example, depending on the teaching, the distal end of the inspiratory tube in a unilimb circuit is either connected at its distal end to a distal fitting with the expiratory tube (in order to avoid dead space at the distal end of a circuit), or it is taught to disconnect the inspiratory tube from the distal

fitting to prevent undesired detachment at the proximal end and avoid dead space during use (e.g., US Patent 4,265,235).

The change of just one tube from corrugated tubing to pleated tubing in a circuit or portion thereof is a significant modification to a breathing circuit due to the large variation in flow characteristics between corrugated and pleated tubing. Pleated tubing can extend to over three to five times its compressed or folded length, and will retain the angle, shape and conformation to which it is manipulated. In contrast, corrugated tubing maintains a substantially consistent length and volume, which can lead to undesired disconnection of such tubing undergoing tension such as that encountered in a typical operating room (e.g., during routine manipulation and/or by the circuit being stepped on). The large differences in pleated tubing and corrugated tubing pose significant unpredictable performance variations and construction challenges in exchanging corrugated tubing with pleated tubing, which discouraged the use of pleated tubing as disclosed by the present application. Despite pleated tubing being available for more than 20 years, no one of skill in the art taught or suggested a unilimb circuit wherein both the inspiratory and expiratory tubes are formed of pleated tubing as recited in the present claims

The invention recited by claim 1 is embodied in a commercial product that has achieved commercial success in a short period of time, which can be substantially attributed to the many benefits of the present inventions and associated unexpected results. The benefits of the present inventions and the long felt needs met by the present inventions further establish these inventions to be both novel and non-obvious. Further, the claimed inventions solve many problems that prior circuits cannot solve.

The unilimb circuit of the present inventions provide a breathing circuit that is multi-functional, having a variable length circuit (extended and contracted) and its flexibility allows it to retain a desired shape, angle or conformation, while allowing spontaneous and assisted ventilation. The ability to adjust the length of the breathing circuits of the present inventions during use produces tremendous advantages and benefits since the same circuit can be extended, for example if the position of the patient needs to be changed during surgery, or when the ventilator or anesthesia machine is moved farther away, without fear of excessive pulling at fittings that can lead

to undesired disconnection. Likewise, the circuit can be compressed to avoid an undesired draping if the anesthesia machine is relocated closer to the patient. This can be done without the need to use different size circuits demanded by use of prior art circuits. The circuits of the present inventions solve multiple problems of prior art circuits, and have the following benefits over prior art circuits:

a) Significant cost savings:

No need to use and dispose of several circuits for the same surgical procedure when the anesthesia machine or ventilator needs to be relocated or when the position of the patient needs to be changed during surgery.

b) Safety:

- Avoids and/or minimizes chances of occlusion due to excessive draping (this often happens when the anesthesia machine is moved and the machine rests on the circuit or a health care provider steps on the circuit).
- Avoids and/or minimizes chances of disconnections or misconnections during the operation, because the same connected circuit is utilized in a variety of lengths and circumstances.
- It maintains a desired conformation or shape of the tubing and maximum control over difficult positioning without pulling and disconnecting the circuit from the airway device such as the endotracheal tube; such disconnection can be crucial as the patient may not receive sufficient oxygenation and/or anesthetics during the procedure.
- The flexibility of the circuit also avoids pushing and/or moving the endotracheal tube which may cause injury of the patient's vocal cord, larynx etc.

c) Storage space and inventory cost savings:

- Only one circuit size needs to be stored.
- Inventory becomes significantly simple.
- Storage space is greatly reduced.

d) One size fits all usages and simplifies inventory:

- Only one size circuit needs to be manufactured.

- Filling orders/requests becomes much simpler and economical for the manufacturer/distributor with less chance of errors.

e) Packaging and shipping:

- Packaging is more compact.
- Shipping becomes simpler and less expensive because the size of the shipping containers are smaller and lighter in weight.

f) Controls the inspiratory/delivery anesthetic concentration ratio:

- Controls airflow volume of the conduits by extending or contracting the breathing conduits.
- Avoids under-anesthetizing the patient during low-flow anesthesia.
- Provides significant savings in anesthetic gases.

g) Convenience:

- Much more convenient for the user, the procurement department of the hospital, and the manufacturing company.

In contrast, the prior art unilimb breathing circuits, such as those taught in the cited Suzuki and Fukunaga patents, have different structures, and their function is limited to a predetermined length circuit as they cannot extend and contract and do not retain a desired angle, shape or conformation.

With regard to Clawson, one of skill in the art would not be led to combine its teachings with that of Suzuki and/or Fukunaga (or other prior art) because it is both inoperative and teaches away from the present invention. Clawson teaches away from the present claims recitation of a distal fitting that can directly connect to a patient airway device since Clawson teaches the use of a single pleated tube to distance the patient from its supply and exhaust lines (i.e., the breathing circuit) in order to reduce tension on the patient airway device. Clawson teaches a single embodiment that includes two pleated tubes connected to a complicated manifold intermediate to the patient and assisted ventilation machine, and does not teach a distal fitting that can be directly connected to a patient airway device as recited in the claims.

The nozzle 100 in Clawson's manifold restricts air flow so severely that a patient could die from severe hypoxic injury, so that Clawson's device would not be useful for

providing spontaneous and assisted ventilation. Clawson's device is designed for a different use, high frequency pulsing of manifold pressure, which requires very high pressures not used for spontaneous and assisted ventilation. One of skill in the art would not be led to modify Clawson's teaching by combining it with prior art circuits for spontaneous and assisted ventilation. For almost two decades since Clawson was published no one of skill in the art recognized that Clawson's manifold could be replaced with a distal fitting that can be directly attached to a patient airway device and that the higher pressures required for Clawson's device and use were not necessary to overcome concerns about insufficient and unpredictable air flow through two coaxial pleated tubes at lower pressures and flows used for conventional spontaneous and assisted ventilation. Further, Clawson's teaching is inoperative because the tubing taught for his circuit would not have sufficient strength to handle the high pressures (i.e., have the low compliance required) for his device to work. Hence, one of skill in the art would be taught away from the present invention by Clawson's teaching of distancing the patient from the supply and exhaust conduits of its circuit (which is also a controversial teaching of increasing dead space – considered undesirable in numerous prior art publications), and would not be led to modify Clawson's inoperative device to accomplish the present inventions due to the different function and requirements of Clawson (i.e., high pressure pulsing versus spontaneous and assisted ventilation). It is clear that the present invention is not obvious to one of ordinary skill in the art over Clawson in combination with Suzuki or with other prior art since almost two decades passed after Clawson's publication and that of Suzuki.

In fact, numerous teachings of unilimb circuits have been available for over 35 years. Unilimb coaxial circuits have been used clinically since about 1972. For example, the Bain circuit disclosed in US Pat. No.3,856,051, issued in 1974, and the F circuit disclosed in US 4,265,235, issued in 1981, both of which predate Clawson. Yet, despite these prior teachings of unilimb circuits and pleated tubing being known, none of the cited documents (i.e., Suzuki, Clawson, or Fukunaga (the present inventor)) recognized that pleated tubing could be used as claimed to achieve the claimed circuit with its numerous benefits. Furthermore, after the disclosures of the Clawson and Suzuki references, numerous circuit manufacturing companies and researchers in the

field sought to improve unilimb circuits as demonstrated by the following U.S. patents: 4,621,634, issued to Nowacki et al. on November 11, 1986; 4,637,384, issued to Schroeder on January 20, 1987; 4,967,744, issued to Chua on Nov. 6, 1990; 5,121,746, issued to Sikora on June 16, 1992; 5,284,160, issued to Dryden on February 8, 1994; 5,404,873, issued to Leagre et al. on April 11, 1995; 5,722,391, issued to Rosenkoetter et al. on May 3, 1998; 5,778,872, issued to Fukunaga et al. on July 14, 1998; 5,823,184, issued to Gross on October 20, 1998; 5,983,891, issued to Fukunaga on November 16, 1999; 5,983,894, issued to Fukunaga on November 16, 1999; 5,983,896, issued to Fukunaga on Nov. 16, 1999; 6,003,5511, issued to Fukunaga on December 21, 1999.

In fact, US Patent 5,823,184, issued to Gross on October 20, 1998, cites Suzuki and Clawson, and the cited Fukunaga patent is based on a patent application by the present inventor filed more than a decade after the publication of Suzuki and Clawson. **Yet, despite almost two decades passing since the publication of Suzuki and Clawson, none of the inventors of these patents, which certainly is a group including persons of at least ordinary if not superior skill in the art, developed an enabling teaching of the present claimed inventions despite the many benefits mentioned above.**

There are also unexpected benefits of the present invention not taught or suggested by the prior art. For example, the ratio of inspired concentration to delivered concentration of anesthetic gases can be optimized by adjusting the circuit volume. This leads to substantial savings of anesthetic gases among other benefits, including those discussed before. Just the cost savings made possible by the present inventions alone demonstrate that if the present inventions had been obvious they would have been introduced years before.

The commercial success of the present inventions also demonstrates that the present inventions are not obvious. The King Systems' web site advertises a circuit, the "UNIVERSAL FLEX2" made in accordance with the present invention which is being sold in place of some of the prior circuits covered by the cited Fukunaga patent, further demonstrating that the present inventions are not obvious over the prior art. (See: http://www.kingsystems.com/PRODUCTS/CircleCircuits/UniversalFlex2/tabid/91/Default.aspx).

In view of the foregoing, it is respectfully requested that the pending claims as amended be allowed.

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